

REMARKS

Claims 1-35 are pending in the application. Claims 3, 4, 9, 10, 13-17, 19-21, and 24-31 are withdrawn from consideration. Claims 1, 2, 5-8, 11, 12, 18, 22, 23 and 32-35 are presently under consideration.

Claims 1 and 7 are presently amended. The amendments do not incorporate new matter into the application.

Rejection under 35 U.S.C. § 112.

The Examiner has rejected claims 1, 2, 5-8, 11, 12, 18, 22, and 23 under 35 U.S.C. § 112, first paragraph, asserting that these claims are not enabled to their full scope. While the applicants do not agree with the Examiner's characterization of lack of enablement, claims 1 and 7 have been amended to facilitate prosecution of the application. Specifically, the recitations relating to interdiction and prevention of interstitial cystitis have been deleted.

As the rejection is no longer applicable, its reconsideration and withdrawal are respectfully requested.

Rejection under 35 U.S.C. § 103.

The Examiner has rejected claims 1, 2, 5-8, 11, 12, 18, 22, and 23 under 35 U.S.C. § 103(a) as being unpatentable over one of

(i) Tu, *et al.* "A Retrospective Analysis of Calcium Glycerophosphate (Prelief) in the Treatment of Food-Sensitive Interstitial Cystitis Patients," Association des Urologues du Quebec ("Tu"), or

(ii) Whitmore, *et al.*, "Survey of the Effect of PRELIEF on Food-Related Exacerbation of Interstitial Cystitis Symptoms," February 16, 2001, Philadelphia 1998-99 ("Whitmore"), or

(iii) Jones, "The Therapeutic Effect of Calcium Glycerophosphate (Prelief) in Interstitial Cystitis," *A Survey of Interstitial Cystitis Support Group (UK) Members*, January, 2000 ("Jones"),

each taken in view of U.S. Patent No. 5,674,527 of Inoue, *et al.* ("Inoue"). As basis for the rejection, the Examiner asserts that Tu teaches the usefulness of a calcium glycerophosphate composition for the treatment of interstitial cystitis. However, the Examiner concedes that Tu does not teach the employment of other salts of glycerophosphate for treating interstitial cystitis. The Examiner asserts that Inoue discloses compositions comprising non-calcium glycerophosphate salts, such as those having the cations of potassium, magnesium, or sodium. The Examiner reasons that a person of ordinary skill in the art would have been motivated to employ a composition comprising a glycerophosphate salt having non-calcium-cation, merely because such glycerophosphate salts are known. The Examiner states: "Therefore, being not employing the particular salt disclosed in the prior art is seen to be an obvious variation from the known method."

The applicants respectfully traverse the rejection.

Tu, Jones and/or Whitmore each disclose the use of calcium glycerophosphate in the treatment of interstitial cystitis. As conceded by the Examiner, no other salts of glycerophosphates are disclosed or suggested for such treatments.

Inoue discloses an intravenous infusion that is administered to supply nutrients for maintenance of a patient's life when oral or nasal feeding is impossible or insufficient. The Inoue infusion includes an electrolyte component that includes the electrolytes necessary to sustain physiological functions, such as sodium electrolytes, potassium electrolytes, calcium electrolytes, magnesium electrolytes, phosphorus electrolytes, and zinc electrolytes, in various suggested forms including magnesium glycerophosphate and potassium glycerophosphate. The infusion preparation is delivered to the patient intravenously and does not pass through or otherwise come in direct contact with the tissues of the bladder.

The Examiner has failed to make a *prima facie* case of obviousness, for she has provided no motivation that would have caused a person of skill the make the combination she proposes in order to arrive at the claimed method. It is well settled that the law requires some teaching, suggestion, or reason to combine the asserted references. The showing of combinability, in whatever form, must be clear and particular.

In the situation at hand, no motivation has been demonstrated, quite simply because none existed. Each of Tu, Jones, and/or Whitmore discusses use of a specific formulation containing

calcium glycerophosphate sold under the commercial name PRELIEF. PRELIEF, as taught in these references can be used with varying efficacy to treat interstitial cystitis. PRELIEF, as would have been known to a person of skill in the art, is administered orally in tablet form.

In contrast, the infusion preparation of Inoue is used to provide basic nutrition to patients who cannot take in nutrition via the digestive tract. The Inoue preparation is a solution containing a human patient's nutritional requirements to sustain life such as sugars, amino acids, electrolytes, and fat emulsions. Notably, the nutritional solution preparation of Inoue is administered intravenously to patients who cannot consume nutrition-containing food in the traditional manner or who cannot absorb nutrition because of an improperly functioning digestive tract. The preparation of Inoue is designed to specifically offer the patient nutrition by bypassing the bladder, the site of interstitial cystitis symptoms. A person of ordinary skill in the art would not have been motivated to select one of the electrolytes of the intravenously administered nutritional preparation of Inoue, form it into a tablet and administer it orally to a patient in order to treat interstitial cystitis, nor would he have had any expectation that such modification of Inoue would have been successful. The Inoue preparation is neither designed to aid in the treatment of interstitial cystitis, or any other bladder ailment, nor is it to be administered orally.

In view of the foregoing, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness based upon the proposed combination. Reconsideration and allowance of the claims at the earliest opportunity are respectfully solicited.

CONCLUSION

In view of the foregoing, it is respectfully submitted that claims 1, 2, 5-8, 11, 12, 18, 22, 23 and 32-35 are compliant with 35 U.S.C. § 112. Moreover, all pending claims are patentable distinguishable over the cited prior art. Thus, it is respectfully requested that the Examiner reconsider and issue a Notice of Allowance at the earliest opportunity.

Respectfully submitted,

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